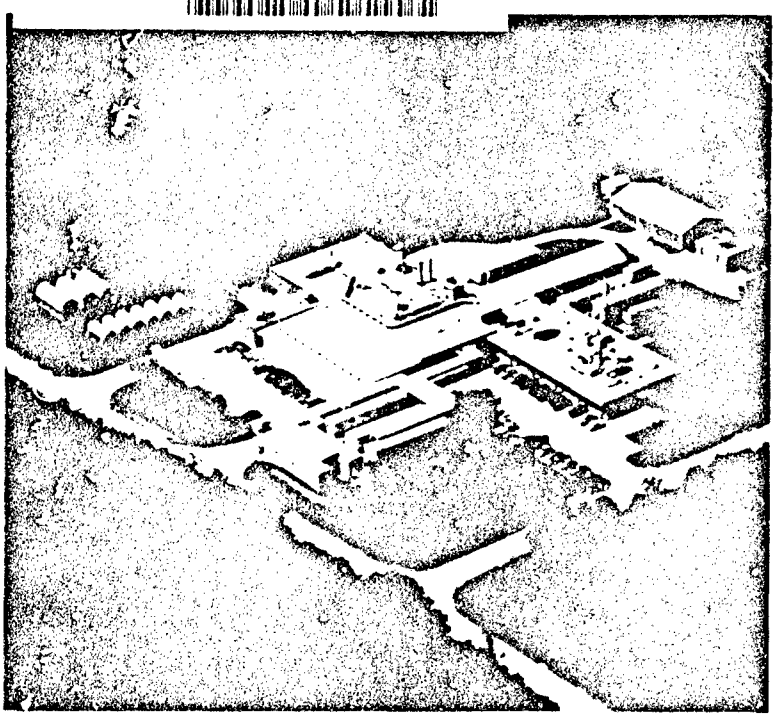

REPORT

FINAL REPORT

TASK 90-17: DECONTAMINABILITY STUDY ON THE U.S. ARMY RESUSCITATION DEVICE, INDIVIDUAL, CHEMICAL (RDIC)

To

U.S ARMY MEDICAL RESEARCH

AND DEVELOPMENT COMMAND

APRIL, 1991

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A study was performed to determine the effect of three commonly used field decontaminants [DS2, super tropical bleach (STB), and the M270 Decontaminating Kit, Individual (DKIE)] on the Resuscitation Device, Chemical, Individual (RDIC). The RDIC system was analyzed to determine which components were accessible to chemical agents and could be degraded by them. The chemical agent susceptibility of the silicone rubber components is the weakest point in the RDIC system. The lack of accessibility of key components to the wetted DKIE wipes and the deterioration of key components by DS2 eliminates these two methods as possible decontaminant methods. STB had no noticeable effects on the RDIC and is recommended as the best field decontamination method.

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Supporting the Medical Chemical Defense Program

on

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to

U.S. ARMY MEDICAL RESEARCH
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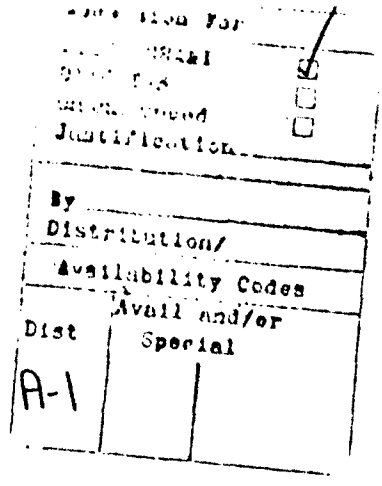

April, 1991

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AND DEVELOPMENT COMMAND

April, 1991

Garrett S. Dill, D.V.M. — Date
Principal Investigator

Richard D. Leonard — Date
Study Director

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TASK 90-17: DECONTAMINABILITY STUDY ON THE U.S. ARMY RESUSCITATION DEVICE, INDIVIDUAL, CHEMICAL (RDIC)

1.0 INTRODUCTION

The U.S. Army through the Resuscitation Device, Individual, Chemical (RDIC) program is developing a portable, manually operated device that provides positive pressure respiratory ventilation/resuscitation--via an oropharyngeal mask or a cricothyroid cannula--to assist in the restoration of normal breathing of a chemical or trauma battlefield casualty, using filtered ambient air. The RDIC has passed through to the Production and Deployment phase, but it was decided to evaluate the decontamination compatibility of the device prior to production.

The Operations Analysis and Planning Department of the Battelle Columbus Division at Columbus, Ohio in support of the Medical Research and Evaluation Facility (MREF) of the Battelle Columbus Operations at West Jefferson, Ohio was assigned Task 90-17 of Contract DAMD17-89-C-9050 to accomplish the above.

2.0 OBJECTIVES

The objective of Task 90-17 is to determine and evaluate the decontaminability of the RDIC.

3.0 EVALUATION

3.1 General Approach

The decontaminability study was conducted in three steps. The first step was to determine which components of the RDIC were accessible to chemical agents during normal use. Next, these components were analyzed for chemical agent susceptibility based on a literature search and information provided by the U.S. Army. Finally, the resuscitator's susceptibility to decontaminants was determined based on laboratory exposure of the RDIC to decontaminants. The combination of these three parameters determined the decontaminability of the resuscitator.

3.2 Accessibility

The accessibility of any component of the RDIC system determines whether that component would become contaminated during normal use and storage. Components that are non-accessible do not normally require decontamination and need not be chemical agent resistant. As a result, defining which components of a system are non-accessible reduces the number of materials that require susceptibility analysis for chemical agents/decontaminants.

3.2.1 Evaluation

Accessibility was determined based on a review of the expected environment in which the RDIC will be employed, its storage system, and its method of use. Accessibility results are outlined in Table 1.

The RDIC was designed to provide filtered, contaminant-free air to a casualty in a chemically contaminated environment. It uses a standard carbon-based (C2) filter to remove contaminants from the ambient air pulled into the resuscitator during expansion of the resuscitator bag. The contaminant-free air then flows to the patient via an oropharyngeal mask or a cricothyroid cannula during compression of the resuscitator bag. The storage system consists of a zip-lock plastic bag and a carrypack made of a thermoplastic and designed similar to a small tool box. This storage system should prevent any liquid contamination reaching the RDIC while in storage; however, it will not prevent vapor penetration.

A cursory look at the resuscitator indicates that all surfaces exposed to the ambient air are accessible to chemical agent vapors and, potentially, chemical agent liquids. A key accessible component in this category is the patient valve housing with outlet valve (ambient air side). All other components except the Inner bag with outlet connector and the inlet valve membrane are also considered accessible due to their normal exposure to the potentially contaminated ambient air.

The previously noted components of the RDIC are exposed to the ambient air on a continuous basis during regular use. Several components not accessible during use could be exposed to contaminated air when the RDIC is removed from the storage bag and placed on the patient. In this category are the patient sides of the face mask, patient inlet valve with mushroom bellows, and the patient valve housing with the outlet valve.

3.2.2 Conclusions and Recommendations

The evaluation in paragraph 3.2.1 noted that all but two components of the RDIC are at least partially accessible in some way to chemical agent vapors/liquids during storage or employment. As a result, they would require decontamination after employment. Contamination of the majority of these components would not prevent using the RDIC while it is contaminated. However, contamination of the patient sides of the face mask, patient inlet valve with mushroom bellows, and the patient valve housing with the outlet valve without decontamination prior to application to the patient would result in directly introducing contaminants to the patient's face and respiratory system.

Preventing exposure of these parts to agent vapors will be difficult, if not impossible, in the field environment. Remediation of this problem is possible by compressing the resuscitator bag just prior to placing the mask to the face of the patient. The resulting exhaust of contaminant free air through the inlet valve/patient valve/mask area will remove any vapor contaminants prior to placing the mask on the patient. This process would serve the same purpose as clearing ones own protective mask during normal masking procedures. Unlike agent vapors, contamination of any of these areas with liquid agents cannot be solved easily and will render the resuscitator useless until decontaminated. Liquid agent contamination of the inlet valve/patient-valve/mask area should be avoided at all times.

3.3 Susceptibility

The susceptibility of a material describes the material's hardness to or degradation by chemical agents/decontaminants. An accessible component should not be susceptible to chemical agents/decontaminants that it would come into contact with during normal use.

3.3.1 Chemical Agents

Susceptibility to chemical agents falls in two categories: degradation of material properties and material sorption/desorption of chemical agents. Degradation of material properties can include loss of tensile strength, flexural strength, or elasticity which results in poor system performance or complete failure. Material sorption/desorption of chemical agents increases the difficulty of decontamination and can result in agent vapor offgassing after decontamination.

3.3.1.1 Method of Evaluation.

The material susceptibility analysis for chemical agents is based on a comprehensive search of available literature by this office and input provided by the U.S. Army Medical Materiel Development Activity (USAMMDA). Susceptibility criteria are based on the requirements of AR 70-71, Nuclear, Biological, and Chemical Contamination Survivability of Army Material. However, test methods used in literature varied significantly. In fact, none of the studies met the strict end-item susceptibility testing criteria in AR 70-71. Therefore, standard criteria were established that would minimally comply with AR 70-71.

3.3.1.2 Results.

Susceptibility results are outlined along with accessibility in the table in Section 4.0.

3.3.1.3 Discussion.

The results of the susceptibility evaluation for contaminants highlight the weak areas of the RDIC system. The silicone rubber valve bellows and membranes are of greatest concern. Silicone rubber traditionally exhibits a high rate of absorbency to chemical agents in liquid form--as a result, the ability to decontaminate silicone rubber components after exposure to liquid agents is suspect. Possible incomplete decontamination of the silicone rubber components of the system can render it hazardous to use, as agent vapor offgassing will immediately result in introduction of the agent vapor into the patient's respiratory system.

The hazards mentioned above assume exposure of the RDIC and all its components to liquid agents. Although a possibility in field use, it would not be expected in normal employment. Storage of the RDIC during chemical attacks and avoidance of contact with liquid agents should be possible without limiting its mission capabilities.

3.3.2 Decontaminants

The knowledge of an item's susceptibility to decontaminants assists in determining how it is affected by decontaminants, what are the best decontaminants to use, and whether it is practical/possible for it to be decontaminated. There are numerous methods to decontaminate equipment and the three most common U.S. Army methods were tested in this evaluation: exposure to a Super Tropical Bleach (STB) slurry, exposure to decontaminating agent DS2, and treatment with the M270, Decontaminating Kit, Individual, Equipment (DKIE).

3.3.2.1 Method of Evaluation.

The military decontamination procedures applied in the decontaminant susceptibility tests are derived from U.S. Army Field Manuals and, in the case of the DKIE, the decontamination kit use instructions. A separate RDIC was used in each test procedure for a total of three devices. The filter canister

was not included in any test procedures, as it would be replaced after each agent exposure and not decontaminated. These tests did not include exposure to chemical agents/simulants prior to decontamination. All three resuscitators underwent leakage and performance testing at the Department of Physiology, Uniformed Services University of the Health Sciences (USUHS) prior to exposure to decontaminants and were returned to USUHS for retesting after the completion of testing at Battelle. As a result, this evaluation does not include an evaluation of the RDIC's performance capabilities, and comments are limited to visual and tactile observations noticed during and after the test procedures. However, also included are observations from previous tests of similar materials.

3.3.2.2 DKIE Decontamination.

Test Procedure

The RDIC was dismantled per its directions for use (see Figure 1). Each component was rinsed with water. Each piece of the RDIC was then wiped with the DKIE cloths in accordance with (IAW) the DKIE instructions for use. The DKIE consists of two cloth wipes. The first, which is prewetted with hydroxyethane (72 ± 2 percent), phenol (10 ± 0.5 percent), sodium hydroxide (5 ± 0.5 percent), ammonia (0.2 ± 0.05 percent), and water, was used to wipe the RDIC for 3 min. The second, which is impregnated with chloramine B and is wetted with hydroxyethane (45 ± 2 percent), zinc chloride (5 ± 0.5 percent), and water, was used for 3 min. The components of the resuscitator were then immersed in water for 1 hr, rinsed with water, dried, photographed, and inspected for deterioration. After the inspection, the RDIC was reassembled and squeezed at 30 cycles/min for 5 min, and any signs of degradation were noted.

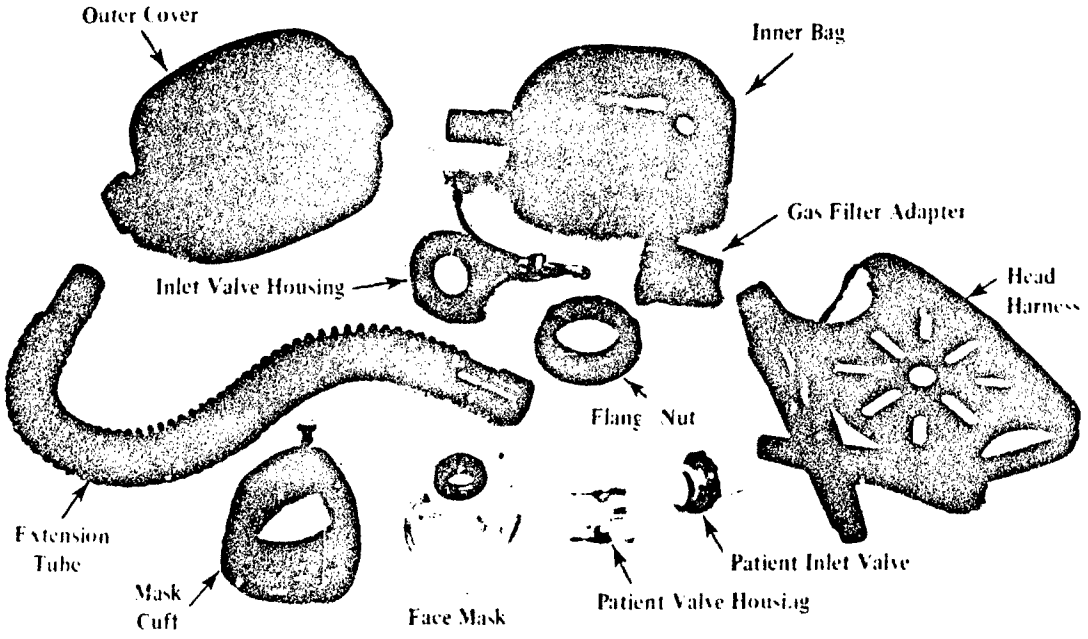


FIGURE 1. DISASSEMBLED RDIC

Evaluation

The exposure of the RDIC to the wetted wipes in the DKIE resulted in no noticeable degradation of the RDIC components. The wipes did leave a white residue that is a common and harmless result of use of the DKIE. The DKIE wipes however do not provide total coverage of the resuscitator, as many areas are inaccessible to the wipes (see Figure 2). The DKIE system is therefore not an acceptable method for complete decontamination and should be limited to removal of gross amounts of liquid contaminants following a chemical agent attack.

3.3.2.3 DS2 Decontamination.

Test Procedure

The RDIC was dismantled per its directions for use (see Figure 1). Each component was then rinsed with water. Each piece of the RDIC was then dipped in Decontaminating Solution 2 (DS2) and allowed to sit for 30 min. At the end of 30 min, the pieces were immersed in water for 1 hr, rinsed with water, dried, photographed, and inspected for deterioration. After the inspection, the RDIC was reassembled and squeezed at 30 cycles/min for 5 min, and any signs of degradation were noted.

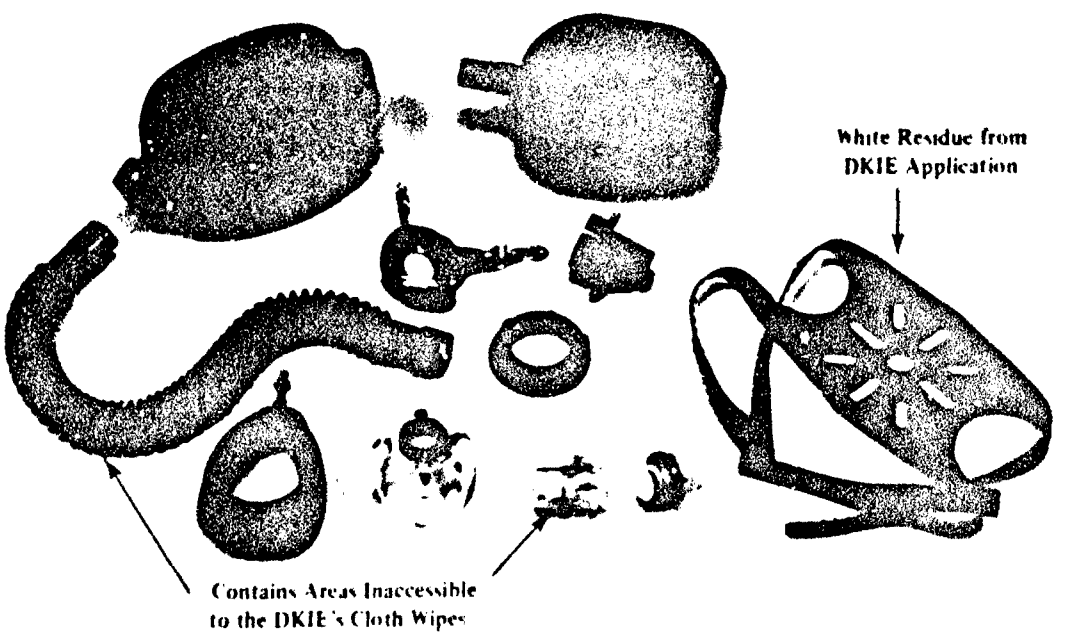
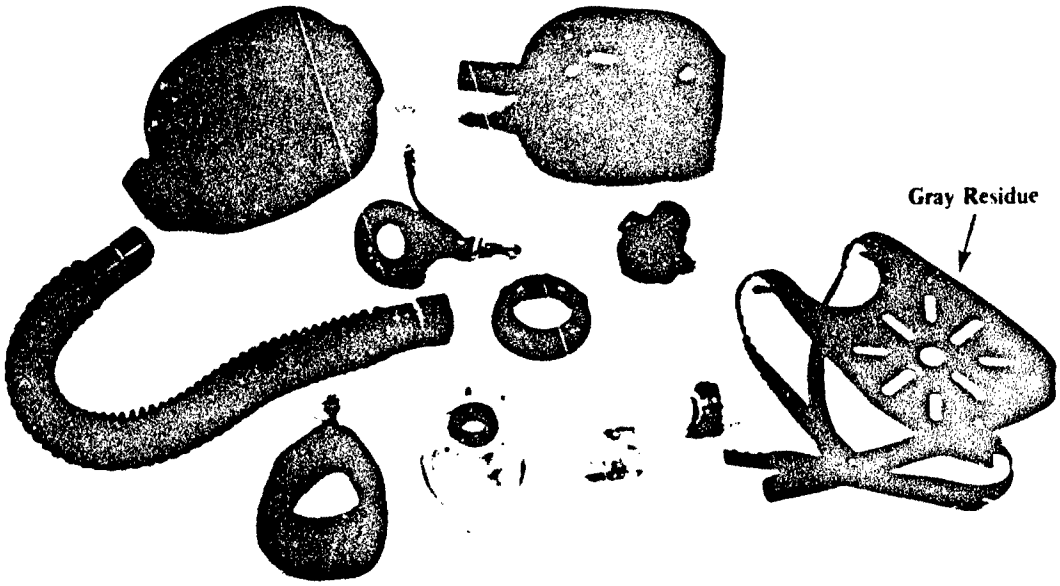


FIGURE 2. DKIF DECONTAMINATION RESULTS

Evaluation

The DS2 decontamination procedure resulted in noticeable degradation of the RDIC (see Figures 3-6). The most extreme deterioration was noted in the components constructed of silicone rubber as expected from similar tests conducted previously (see references 1 and 2). Silicone rubber components include the inlet valve, patient inlet valve with mushroom bellows, outlet valve, and the inner gasket of the gas filter adapter. Additional problems were noted in the extension tube with a reduction in flexibility of the tube and a color change (black to white) of the bonding cement between the extension tube and its end connectors (see Figure 4). Discoloration was also noticed in the mask cuff, although it did not seem to affect performance (see Figure 6). On a general note, the mushroom bellows retained water during the rinsing procedures of all decontamination operations (see Figure 5).

The overall performance of the RDIC during the DS2 decontamination was unacceptable. The degradation of the key silicone rubber components will only get worse with additional contamination/decontamination cycles which will result in eventual failure. The deterioration of the extension tube will also increase over time. The noted points of degradation could seriously affect the future performance of the resuscitator, and unless the materials used in the construction are changed, the RDIC is not decontaminable with DS2.



Note: Refer to following figures for other components

FIGURE 3. DS2 DECONTAMINATION RESULTS 1

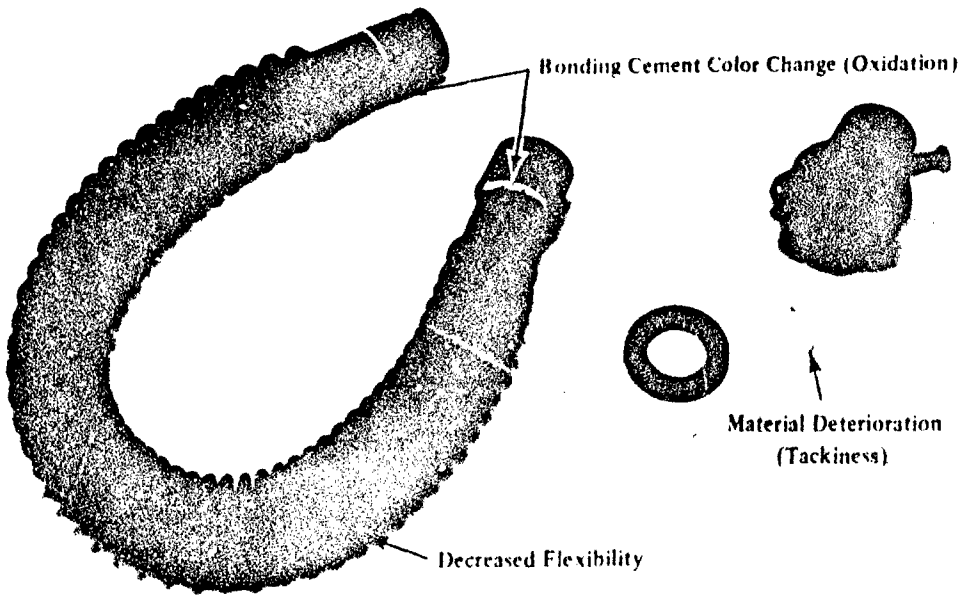


FIGURE 4. DS2 DECONTAMINATION RESULTS 2

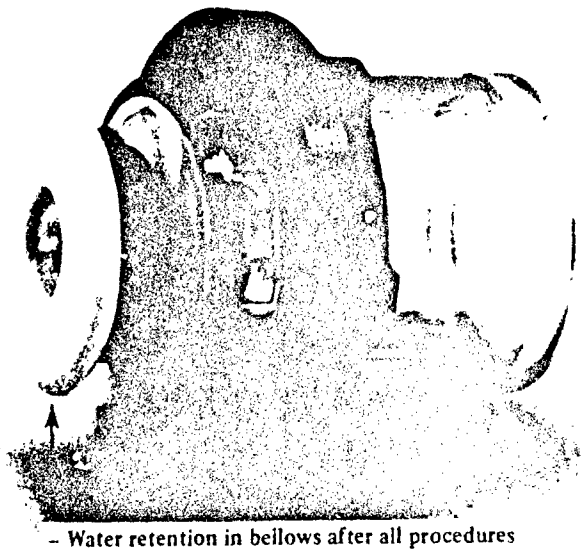


FIGURE 5. DS2 DECONTAMINATION RESULTS 3

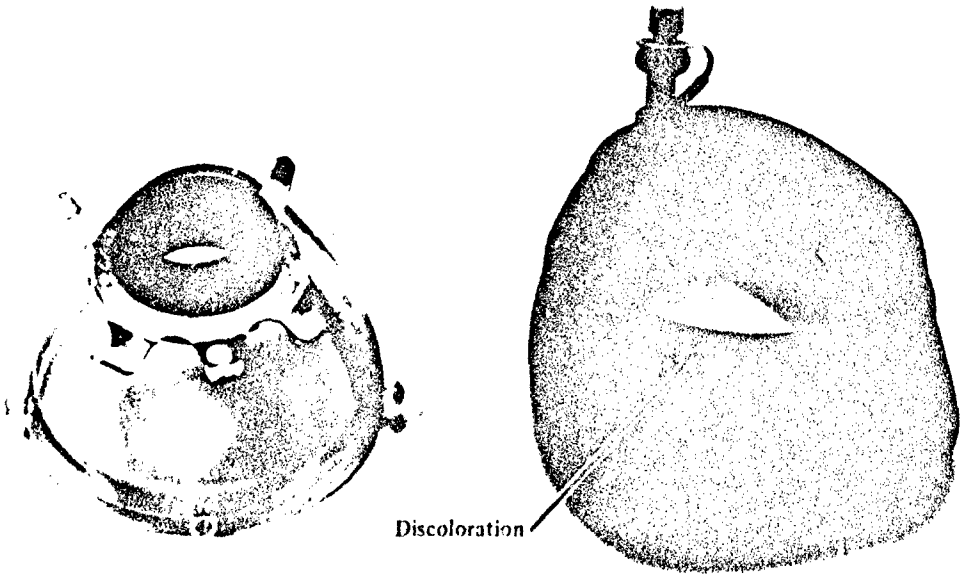


FIGURE 6. DS2 DECONTAMINATION RESULTS 4

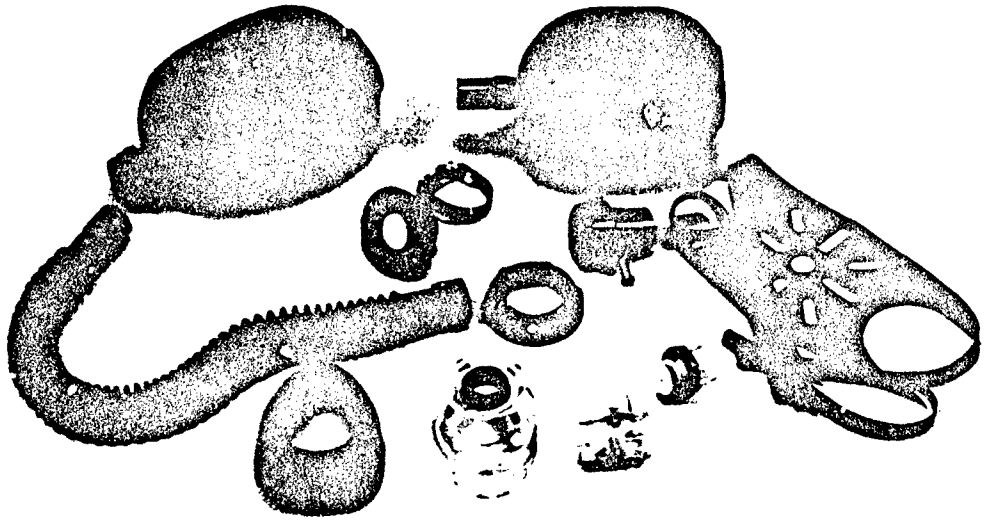
3.3.2.4 STB Slurry Decontamination.

Test Procedure

The RDIC was dismantled per its directions for use (see Figure 1). Each component was rinsed with water. The STB slurry mix was prepared in accordance with FM 3-5. Due to the unavailability of STB a substitute, Olympic Pool Chlor 65, was used. A solution containing 5 lbs of STB (Pool Chlor 65) per 1 gallon of water was used. Olympic Pool Chlor 65 is a granular mixture with 65% calcium hypochlorite and 35% inert ingredients. Each piece of the RDIC was immersed in the STB slurry for 10 min. At the end of 10 min, the pieces were removed from the slurry and immersed in water for 1 hr, rinsed with water, dried, photographed, and inspected for deterioration. After the inspection, the RDIC was reassembled and squeezed at 30 cycles/min for 5 min, and any signs of degradation were noted.

Evaluation

The STB slurry caused no visual or tactile degradation of the RDIC. The only noticeable effect was the presence of a thin white film on all of the components that is not expected to affect the resuscitator's performance (see Figure 7). These observations correspond with those in references 1 and 2. The use of an STB slurry to decontaminate the RDIC will be the most effective of the three methods tested. This procedure caused no noticeable degradation of performance and is an effective method for chemical agent removal.



Note: White residue on all parts.

FIGURE 7. STB SLURRY DECONTAMINATION RESULTS

4.0 SUMMARY

The three Army RDICs arrived at Battelle following leakage and performance testing at USUHS. Battelle was tasked to conduct a decontaminability study of the resuscitators by performing a different standard U.S. Army field decontamination procedure on each of the three devices. Prior to conducting the decontamination procedures, the RDIC system was analyzed to determine which components were accessible to chemical agents and could be degraded by them. The results of this analysis are restated in Table 1. The chemical agent susceptibility of the silicone rubber components is the weakest point in the RDIC system. Previously, live agent testing had confirmed that exposure of silicone rubber to liquid chemical agents would produce rapid deterioration. Information on the testing and susceptibility of silicone rubber against chemical agent vapors could not be located. Since it has not been demonstrated that silicone rubber items contaminated with liquid

chemical agents can be decontaminated, it is imperative that any operational instructions published for the RDIC include procedures to prevent its contamination by liquid chemical agents. The susceptibility of the resuscitator to decontaminants is also restated in Table 1. The lack of accessibility of contaminated components to the wetted DKIE wipes and the deterioration of key components by DS2 eliminates these two methods as possible decontaminant methods. STB had no noticeable effects on the RDIC and is recommended as the best field decontamination method. It is also recommended that, when possible, the disinfecting or sterilizing methods recommended in the directions for use be used following normal decontamination to remove any remaining decontaminants.

TABLE 1. RESULTS OF ACCESSIBILITY AND SUSCEPTIBILITY ANALYSIS

			Susceptibility				
			Chemical Agent*		Decontaminants		
Component	Material	Accessibility	G-Series	H-Series	DS2	STB	DKIE
Inner Bag	EPDM Rubber	No	NA	NA	Pass	Pass	Pass
Outer Cover	Butyl Rubber	Yes	Pass	Pass	Pass	Pass	Pass
Inlet Valve Housing	Polyacetal	Yes	Pass	Pass	Pass	Pass	Pass
Inlet Valve	Silicone Rubber	No	NA	NA	Fail	Pass	Pass
Gas Filter Adapter	Polyacetal	Yes	Pass	Pass	Pass	Pass	Pass
Adapter Inner Gasket	Silicone Rubber	No	NA	NA	Fail	Pass	Pass
Adapter Outer Gasket	Unknown	No	NA	NA	Pass	Pass	Pass
Hanging Strap	EPDM Rubber	Yes	Marginal	Marginal	Pass	Pass	Pass
Flange Nut	Polyacetal	Yes	Pass	Pass	Pass	Pass	Pass
Head Harness	Unknown	Yes	Unknown	Unknown	Marginal	Pass	Pass
Patient Valve Housing	Polysulphone	Yes	Pass	Marginal	Pass	Pass	Pass
Patient Inlet Valve	Silicone Rubber	Yes	Fail	Fail	Fail	Pass	Pass
Outlet Valve	Silicone Rubber	Yes	Fail	Fail	Fail	Pass	Pass
Mask Dome	Polysulphone	Yes	Pass	Marginal	Pass	Pass	Pass
Mask Cuff	N.R. Latex	Yes	Marginal	Marginal	Marginal	Pass	Pass
Extension Tube	Unknown	Yes	Unknown	Unknown	Marginal	Pass	Pass

*Chemical agent susceptibility based on references 2 and 3.

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